

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY)	MDL NO. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	CIVIL ACTION: 01-CV-12257-PBS
)	
)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>)	Magistrate Judge Marianne B. Bowler
<i>Inc. v. Abbott Laboratories, Inc.,</i>)	
No. 06-CV-11337-PBS; <i>U.S. ex rel. Ven-A-</i>)	
<i>Care of the Florida Keys, Inc. v. Dey, Inc. et</i>		
<i>al.</i> , No. 05-11084-PBS		

**ABBOTT LABORATORIES INC. AND DEY, INC., DEY, L.P., AND DEY, L.P., INC.'S
REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS'
MOTIONS FOR A FINDING OF SPOILIATION AND FOR SANCTIONS**

INTRODUCTION

For more than a decade after Ven-A-Care filed its initial *qui tam* complaint in 1995, DOJ admittedly engaged in a widespread, one-sided discovery campaign against drug manufacturers. In its own words, DOJ lawyers criss-crossed the country with a “non-stop agenda” of meetings with state and federal officials and “aggressively pursued settlement negotiations” with defense counsel. Yet, as it actively pursued an investigation in service of Ven-A-Care’s sealed lawsuit, DOJ readily admits it did not issue any sort of record hold to preserve documents from relevant government entities until at least 2004. Documents crucial to the defense of this case—paper, emails, claims data, and more—were lost while DOJ pursued evidence to advance its case.

One might reasonably expect an explanation from a litigant facing that kind of record. DOJ instead dismisses the spoliation issue entirely. It does not tell the Court that it took steps to timely and diligently preserve documents. Rather, DOJ claims that it had no duty to preserve evidence during the decade that it kept these cases under seal, investigating and pursuing settlements from defendants. The Ven-A-Care under-seal complaints, DOJ tells the Court, acted only to toll the statute of limitations—thereby maximizing DOJ’s claimed damages. It had no bearing at all, DOJ argues, on any document preservation obligations.

Lacking any authority to excuse its failure to preserve evidence, DOJ resorts to specious arguments about the discoverability and relevance of evidence. In its view, DOJ had the unilateral authority to decide what information from governmental entities should be preserved during the decade these cases languished under seal. DOJ thinks it can assert blanket privileges and fail to preserve evidence because, in *these* cases, the rules are somehow different. The law does not afford DOJ, or any other litigant, that discretion. Indeed, courts across the country, including this one, have squarely rejected DOJ’s post-hoc, self-interested position on the discoverability and relevance of what it calls “government knowledge” evidence. Such courts,

including this one, have ruled that evidence of conscious and deliberate policy choices for Medicare and Medicaid payments is not only discoverable, but admissible, in AWP trials. Here, because DOJ did not take appropriate steps to preserve evidence, Defendants and this Court *will never know* the full extent of what was lost, including the fuller testimony of witnesses whose memories would have been aided by the spoliated documents. The Government's failure to meet its legal and ethical obligations must have consequences.

Finally, DOJ attempts to marginalize the importance of information known to be lost. In so doing, DOJ does not address most of the specific examples identified in Defendants' briefs. What DOJ does address, it dismisses with a wave. For example, the email that New York's Pharmacy Program Director Richard Butt circulated to his state colleagues in 2006—advising them to “get rid of any papers” relevant to AWP litigation so they would not be subject to discovery by Defendants—DOJ describes as “benign.”

The Court should not be so dismissive of DOJ's failure to preserve evidence. It should hold that the Government has spoliated evidence relevant to the defense of this case, and impose appropriate sanctions. Given the materiality of the conduct, Defendants request the Court to hold a separate hearing, before it considers summary judgment motions, to address spoliation issues.

ARGUMENT

I. EVEN THOUGH DOJ HAS ACTIVELY LITIGATED THIS CASE SINCE 1995, IT DID NOT TAKE TIMELY STEPS TO PRESERVE EVIDENCE.

DOJ contends that the “determination of the precise date on which a preservation obligation arose . . . is not critical.” (Dkt. No. 6270 at 26.) The settled law contradicts DOJ's attempt to avoid the issue. *See Zubulake v. UBS Warburg LLC*, 220 F.R.D. 212, 216 (S.D.N.Y. 2003). As the Court knows, “[i]t is the duty of the United States, *no less than any other party before this court*, to ensure, through its agents, that documents relevant to a case are preserved.”

United Med. Supply Co. v. United States, 77 Fed. Cl. 257, 274 (2007) (emphasis added). The proper spoliation analysis must begin with when the duty to preserve evidence arose.

At a minimum, the duty to preserve evidence “arises when the party has notice that the evidence is relevant to litigation or when a party should have known that the evidence may be relevant to future litigation.” *Zubulake*, 220 F.R.D. at 216 (internal quotation marks omitted). DOJ does not provide any authority to dispute the obvious proposition that *the actual filing of a complaint* gives rise to preservation duties. Indeed, in *Miller v. Holzmman*, No. 95-01231, 2007 WL 172327, at *3-6 (D.D.C. Jan. 17, 2007), the district court held that the relator’s filing of an FCA *qui tam* complaint triggered the Government’s duty to preserve evidence. In this very MDL, Magistrate Judge Bowler rejected the State of Nevada’s “imminent litigation” standard, holding that a duty to preserve arose when Nevada’s MFCU sent letters to defendants requesting evidence about AWP pricing—20 months before anyone filed a complaint.¹ (*See* Report and Recommendation, *In re Pharm. Indus. Avg. Wholesale Price Litig.*, MDL No. 1456, at 19-20 (D. Mass. Mar. 14, 2007) (“Nevada R&R”)); *see also Bayoil, S.A. v. Polembros Shipping Ltd.*, 196 F.R.D. 479, 483 (S.D. Tex. 2000) (“Notice does not have to be of actual litigation, but can concern ‘potential’ litigation. Otherwise, any person could shred documents to their heart’s content before suit is brought without fear of sanction.”) (internal citation omitted).

DOJ’s only response to these basic propositions (other than erroneously claiming that they are “not supported by the case law” (Dkt. No. 6270 at 24)) is a broad policy argument that “[u]sing the filing date of a *qui tam* to trigger a preservation obligation” would be too difficult to implement because of the number of *qui tams* initiated each year. (*Id.*) This response goes too far. This Court need not decide whether the Government must implement a litigation hold every time a *qui tam* is filed. The Court need only decide whether a hold should have been instituted

¹ DOJ began issuing subpoenas to Abbott seeking similar information in early 1996. (Dkt. No. 6097 at 2.)

when *these* cases were filed.

That question is easier to answer than DOJ suggests precisely because these were not run-of-the-mill *qui tam* cases. Within months of Ven-A-Care's initial 1995 complaint, DOJ was meeting to discuss Ven-A-Care's allegations with top CMS officials, including representatives of the HHS Office of General Counsel and senior operational officials responsible for drug payment policy. This meeting was quickly followed by "many" meetings with state officials, and then the controversial "DOJ AWP" project. Despite languishing under seal for a decade, this litigation was clearly relevant to drug policy issues at Medicare and Medicaid the day it was filed.

DOJ's actions during the seal period leave no doubt that it anticipated litigation long before, as it now claims, it "began litigation with only three defendants in 2006." (Dkt. No. 6270 at 24.) DOJ's *ex parte* filings with the Florida district court reveal a one-sided discovery effort to influence witnesses and collect the very type of evidence it now claims is irrelevant, including:

- "[M]any meetings and conferences [that] have been held with representatives of the Medicaid programs of the states of Florida, Texas, and New Jersey, along with preliminary discussions with the Medicaid programs of other states" (Ex. A);
- "[A] non-stop agenda of meetings and telephone conferences with numerous parties," including "witness interviews across the country" and "[m]any other meetings in at least five states . . . among counsel for the United States and the representatives of the 47 state Medicaid Fraud Control Units actively participating in the assessment of this qui tam matter" (Exs. B & C);
- An "informal working relationship with the Executive Committee of NAMFCU in order to facilitate the identification of witnesses and evidence relevant to the allegations" (Ex. D); and
- The creation of "an electronic database for storage and review of the thousands of documents" to "share . . . documents" with Medicaid officials and coordinate discovery (*Id.*).

These actions, and DOJ's professed goal to "push[] through as many settlements as possible prior to commencing litigation" (Ex. E), establish conclusively that DOJ anticipated litigation with defendants who declined to settle. Much less has been held to trigger preservation

obligations. *See, e.g., In re Napster, Inc. Copyright Litig.*, 462 F. Supp. 2d 1060, 1069 (N.D. Cal. 2006) (defendant's duty to preserve arose three years before complaint was filed when defendant had a meeting with a music company executive who advised of potential for lawsuit).

DOJ knew at the outset that documents from state and federal agencies would be sought in discovery. Indeed, in a September 30, 1999 letter to Abbott's counsel, the DOJ readily acknowledged Defendants' "government knowledge defense": "During the course of our investigation, we have become aware of the assertion that the 'government' had knowledge that AWP is not indicative of providers' actual acquisition cost for pharmaceuticals." (Ex. F). That letter even laid out how DOJ would "counter" that defense. (*Id.*) In 2000, defense counsel outlined the importance of government evidence and specifically asked DOJ to maintain evidence from state and federal agencies. (*See* Dkt. No. 6097, Ex. Q.) This request gave "explicit notice of the duty to preserve." *Optowave Co. v. Nikitin*, No. 6:05-cv-1083-Orl-22DAB, 2006 WL 3231422, at *10-11 (M.D. Fla. Nov. 7, 2006). DOJ ignores that request entirely in its response to this motion, just as it ignored the request when it was initially made.

While DOJ asserts that it would have been too difficult to preserve evidence in these cases, it offers no support for that assertion. To the contrary, CMS's Julie Boughn testified that it would have been easy to retain and store emails, and that CMS does so often for the OIG. (Ex. G at 223:14-229:5.) Nor is there any evidence that the belated AWP litigation holds eventually implemented by CMS and some states somehow crippled those agencies. The fact that preservation may be costly does not excuse wholesale abdication of preservation obligations, particularly when DOJ is simultaneously seeking hundreds of millions of dollars from Defendants.² In any event, the question of burden goes to the *scope* of the litigation hold, not

² *See* The Sedona Conference, *The Sedona Conference Commentary on Legal Holds: The Trigger and the Process* 6 (2007) ("[T]he trigger point for a small dispute where the risk of litigation is minor might occur at a later point than for a dispute that is significant in terms of business risk or financial consequences.").

when or whether it should be implemented. *See Zubulake*, 220 F.R.D. at 216-17.

The hypocrisy of DOJ's position is most apparent when one compares it to DOJ's positions on the statute of limitations and privilege. DOJ contends that the "relator's [1995] complaint . . . is the operative complaint for statute of limitations purposes" (Dkt. No. 4661 at 4), arguing that the "scheme at issue in the relator's and the United States' complaints is the same." (*Id.* at 15). In contrast, when the issue is DOJ's unmet duty to preserve evidence, DOJ conveniently suggests that Ven-A-Care's *qui tams* have no legal effect. Similarly, DOJ has withheld, as work-product, scores of documents created during its prolonged investigation.³ But work-product protection applies only to documents which "'can be fairly said to have been prepared or obtained *because of* the prospect of litigation,'" and only if there is "something more than a mere remote possibility of litigation." *See In re Grand Jury Subpoena*, 220 F.R.D. 130, 146-48 (D. Mass. 2004) (citations omitted). Again, DOJ treats the *qui tam* as litigation (or at least foreseeable litigation) only when it produces results favorable to the Government.

In sum, DOJ views these lawsuits as a one-way street where it is unfettered by the rules of procedure and has the full advantage of every presumptive protection. The Court should not embrace such an unjust approach to litigation. Defendants request a finding that the Government's duty to preserve evidence clearly arose, at the latest, in 1995.

II. WHEN THE GOVERNMENT ULTIMATELY DID ATTEMPT TO PRESERVE EVIDENCE, YEARS AFTER THIS CASE WAS FILED, ITS EFFORTS WERE WOEFULLY INADEQUATE.

Once the duty to preserve is triggered, a party "*must* suspend its routine document retention/destruction policy and put in place a 'litigation hold' to ensure the preservation of relevant documents" from the "key players" in the case. *Zubulake*, 220 F.R.D. at 218 (emphasis

³ (*See, e.g.*, Ex. H at HHD919-0742-1579 (privilege entry for undated document described as a "Binder" concerning "Materials from DOJ conference re prosecution of health care fraud related to pharmaceutical companies").) DOJ refused to produce or even log its investigative files.

added). DOJ did not remotely satisfy those obligations. For one thing, DOJ's opposition admits that it did not issue any AWP-related litigation holds to state or federal agencies until at least 2004. (Dkt. No. 6270 at 22-24.) Because the duty to preserve arose in 1995, DOJ's preservation obligation was not met. Further, DOJ has refused to provide unredacted copies of the belated 2004 hold, preventing Defendants and this Court from evaluating its adequacy. (Ex. I.) So long as DOJ continues to redact the specifics of that hold, the Court cannot rely on it as any evidence at all of preservation efforts. *See In re eBay Seller Antitrust Litig.*, No. C 07-01882 JF (RS), 2007 WL 2852364, at *2 (N.D. Cal. Oct. 2, 2007) (opposing side is "entitled to know what kinds and categories of [information a party's] employees were instructed to preserve and collect, and what specific actions they were instructed to undertake to that end").

Regardless, the belated 2004 hold was far too narrow in scope. Recall that DOJ worked extensively with state officials throughout its investigation of these cases, touting that work in its requests for extensions of the seal. If the states' information was significant to DOJ's investigation, it is indisputably relevant to this litigation—a fact that has been confirmed in discovery taken by Defendants. But the 2004 litigation hold was directed only at CMS, excluding the states and OIG. Only in late 2006 did DOJ purportedly take any steps to preserve evidence from the states. (*See* Ex. J (Government's response to Roxane interrogatory: "[I]n November 2006, the United States issued a request to all directors of State Medicaid Fraud Control Units to preserve documents concerning State Medicaid payments for drugs.").)

DOJ's response brief does not explain its failure to timely preserve evidence from the vast majority of sources it should have covered. DOJ instead focuses on irrelevant and inadequate actions taken by CMS and Medicare carriers in other, unrelated matters, perhaps hoping to convince the Court that those efforts obviated any need to issue new or expanded

preservation directives relating to these massive cases. (Dkt. No. 6270 at 22.) The facts directly contradict DOJ's position here. As to the Medicare carriers, the 1992 instruction to retain "Medicare claims and payment records" did nothing to preserve documents from CMS itself, let alone the states or OIG. (Ex. K at HHD043-0008.) It did not even cover the key evidence needed from carriers here, the pricing arrays by which payment amounts were determined.

As to CMS, DOJ relies heavily on the notion that "CMS has long had in place record retention policies which provide that large portions of the agency's records are maintained in perpetuity." (Dkt. No. 6270 at 22.) Courts have consistently held that ordinary retention policies are no substitute for a litigation hold. *See Lewy v. Remington Arms Co.*, 836 F.2d 1104, 1112 (8th Cir. 1988) (a party "cannot blindly destroy documents and expect to be shielded by a seemingly innocuous document retention policy"); *Micron Tech., Inc. v. Rambus Inc.*, 255 F.R.D. 135, 148 (D. Del. 2009) (same); *Renda Marine, Inc. v. United States*, 58 Fed. Cl. 57, 60-61 (2003).

The very CMS retention policies cited by DOJ actually demonstrate why they are no substitute for an adequate litigation hold. It is well established that "normal procedures for destruction of documents must . . . be suspended when a party is on notice that they may be relevant to litigation," and that the "failure to make an adequate search of such documents before their destruction may be evidence of bad faith." *DaimlerChrysler Motors v. Bill Davis Racing, Inc.*, No. Civ.A. 03-72265, 2005 WL 3502172, at *1 (E.D. Mich. Dec. 22, 2005). Here, CMS's retention policies show that it regularly and systematically *destroyed* documents unless a litigation hold was in place. For example, a January 29, 1999 email announces that "E-mail storage capacity has been stressed to a critical stage" and that, as a result, "on February 12, 1999, HCFA will begin deleting E-mail messages older than 180 days" (Ex. L at HHC015-0762.)

Employees were given advance notice so that they could print out and retain documents that constituted an “agency record.” (*Id.*) One criterion for whether a document was an “agency record” was whether it had “legal value,” which CMS equated to whether “*it has been identified under a preservation order.*” (*Id.* at HHC015-0763; Ex. M at 105:9-12.)⁴ DOJ’s “reasoning”—documents were retained if they were subject to a preservation order, but a preservation order was unnecessary because of CMS’s retention policies—is both circular and flawed. There can be no debate about the need for a proper litigation hold to ensure retention of relevant evidence. These cases are no different. The admitted absence of a proper, timely litigation hold leads to the obvious presumption that relevant evidence was destroyed.

DOJ also cites testimony that CMS personnel were told to “keep hard copies of anything important.” (Dkt. No. 6270 at 22 (citing testimony from CMS’s M. Bowen).) But Magistrate Judge Bowler correctly rejected that same argument in the Nevada case. (*See Nevada R&R* at 3: “Nevada again did not enact a litigation disposition hold or begin document preservation. Rather, Nevada Medicaid acknowledged that it preserved only whatever documents individual employees retained as being ‘important or useful to them for work.’”); *see also Goodman v. Praxair Servs.*, No. MJG-04-391, 2009 WL 1955805, at *17 n.12 (D. Md. July 7, 2009) (“The argument of an accused spoliator that it did not violate its duty to preserve evidence because it retained the ‘relevant’ information and only deleted ‘irrelevant’ information *rings particularly hollow*. The ultimate decision of what is relevant is not determined by a party’s subjective assessment filtered through its own perception of self-interest.”) (emphasis added).

Finally, DOJ stresses that a narrow part of CMS known as the Office of Strategic

⁴ As discussed in Abbott’s opening brief, CMS’s regular practice is to destroy an employee’s electronic files within 30 days after she leaves CMS. (Dkt. No. 6097 at 11.) Nearly all of the employees identified by the Government as being primarily responsible for CMS Medicare and Medicaid drug policy have left CMS, a fact the DOJ does not dispute. (*Id.*) Disturbingly, according to CMS’s Julie Boughn, CMS “did not take any steps to preserve” the email and other electronic documents of these witnesses when they left CMS. (*Id.*)

Operations and Regulatory Affairs (“OSORA”), which wrote CMS’s regulations, maintained some regulatory documents in perpetuity. (*See* Dkt. No. 6270 at 22.) But the fact that OSORA may have retained regulatory records—many of which are not in evidence in these cases because they are being withheld under an assertion of the deliberative process privilege—is no answer to the un-rebutted proof that the rest of CMS, including its Administrators and the officials responsible for drug pricing and policy, did not retain documents. (*See* Dkt. No. 6097 at 11-12.)

In sum, the Government’s untimely preservation efforts were patently inadequate. In fact, the document policies that DOJ cites encouraged the destruction of relevant documents.

III. THE GOVERNMENT’S SHIRKING OF ITS CLEAR DUTY TO PRESERVE RELEVANT EVIDENCE HAS CAUSED SPOILIATION.

In light of the foregoing, DOJ’s assertion that “no spoliation of any relevant evidence occurred here” cannot be taken seriously. (Dkt. No. 6270 at 4.) It goes without saying that, because DOJ failed to institute a litigation hold, neither it, any Defendant, nor the Court knows what has been lost. As Magistrate Judge Bowler aptly observed in the Nevada case:

Nevada seeks to create an insurmountable catch-22 by claiming that defendants are not entitled to the sanctions they seek without producing evidence about what the destroyed evidence would prove. For example, Nevada contends that it should not be sanctioned for destroying email communications because defendants can produce no evidence about the contents of those emails. . . Thus, under Nevada’s argument, it may destroy documents with impunity because destroying documents prevents their discovery thereby denying defendants the necessary information about the documents.

(Nevada R&R at 22.)⁵ DOJ’s assertions ring just as hollow as Nevada’s did.

In this case, the Court also has before it evidence of material that was *actually destroyed*.

That evidence is likely only the tip of the iceberg.

⁵ *See also Goodman*, 2009 WL 1955805, at *17 (“Additionally, Tracer/PSI’s failure to issue a litigation hold prevents the Court from determining the exact number of relevant emails, memoranda, or documents from the key players that were not preserved.”); *See Leon v. IDX Sys. Corp.*, 464 F.3d 951, 959 (9th Cir. 2006) (“[B]ecause the relevance of [spoliated] documents cannot be clearly ascertained . . . a party can hardly assert any presumption of irrelevance as to the destroyed documents.”); *Google, Inc. v. Am. Blind & Wallpaper Factory, Inc.*, No. C03-5340 JF (RS), 2007 WL 1848665, at *5 (N.D. Cal. June 27, 2007).

A. Spoliation At The State Level.

DOJ's explanation of the 2006 email from New York's Richard Butt underscores the troubling nature of DOJ's cavalier attitude to the issues raised by these motions. Keen to share his own lessons learned from AWP litigation in New York, Mr. Butt explicitly advises his Medicaid colleagues in other states to "get rid of any papers" that attorneys representing drug manufacturers might request in discovery, and to do so before "litigation has begun." (Ex. N.) Remarkably, this email causes DOJ no concern. Rather, DOJ characterizes this direction as merely "a benign expression of one individual's frustration" with the burdens of AWP litigation. (Dkt. No. 6270 at 32.) To the contrary, the email explicitly reveals what has been occurring with respect to discovery in these cases: there have been remarkably few documents, and fewer electronic productions (such as emails) in a case of this size. There is nothing ambiguous about the nature and purpose of this email.

In a further attempt to minimize Mr. Butt's email, DOJ asserts: "If New York officials had actually set out to spoliage documents which arguably could be construed as damaging to their case, presumably the first document that would have been destroyed is the one appended to Abbott's brief." (*Id.*) It appears that New York and many other states may have done just that. Defendants obtained the email only from Georgia Medicaid. Indeed, although representatives from nearly all of the states were copied on the email, to the best of Defendants' knowledge Georgia is the only state to have produced it in discovery. The absence of this email in the productions of other states speaks for itself. To make matters worse, DOJ and others have sought to reclaim the email with specious, after-the-fact claims of "privilege."

Mr. Butt's email is not the only evidence of spoliation at the state level. Appendix A to Abbott's opening brief sets forth extensive evidence of spoliation at the states, including:

- Nesser (OK): "There are no documents available for me to reference those [pre-May

2001] time periods. . . . Q. Are you aware that Oklahoma Medicaid only produced about 10 documents in this case? A. Yes.”);

- Shapiro (MA): “They [correspondence, memoranda, and notes] were all shredded.”;
- Young (RI): “my drives were all erased”;
- McCormick (ME): “we destroyed some documents because we didn’t have as much storage in this new building”;
- Campana (AK): “I don’t know if those particular memos were saved.”;
- Terrebonne (LA): “Some of them are probably kept, some of them are probably not kept.”;
- Wiberg (MN): “Q. When you were going through the process of deciding what to keep, what to archive, what to throw away . . . , were . . . documents need[ed] to be retained for this case [at] all entered into that equation. A. No. This case? No.”; and
- Tomlinson (VA): “2003 was the year that we made—there was—there was a major change in or information system. And most information in the agency does not go back beyond that.”

Such wholesale destruction can hardly be called “benign.”

Finally, DOJ does not mention the almost universal destruction of the “Relationship Between AWP and Pharmacy Cost” survey circulated by South Dakota in 1995. (*See* Dkt. No. 6097 at 15-16.) Nor does it address the destruction of the Medicaid Pharmacy Bulletins or Ven-A-Care’s “continuing education project,” discussed in Abbott’s opening memorandum.⁶

B. Spoliation At The Federal Level.

DOJ’s response to the spoliation of evidence at the federal level is similarly dismissive. For example, rather than respond to unrebutted evidence of the wholesale deletion of emails from former Administrators to other key personnel (*see* Dkt. No. 6097 at 10-12), DOJ instead

⁶ Indeed, Abbott recently learned of another “survey” related to an “investigation” by the New York MFCU in 1998 into the very type of Abbott drugs at issue here, including vancomycin, dextrose, and sodium chloride. (*See* Ex. O.) The survey asks several important questions, such as: “If your state had known about possible deceptive pricing by the manufacturers (e.g., deep discounts for non-government payer), what effect would this have had on the administration of your pharmacy pricing program?” (*Id.* at AWP-IL-0047522.) The states’ responses likely contain factual information that should have been produced in discovery. Yet, like the South Dakota survey, Illinois is the only state to Defendants’ knowledge to have produced material related to the survey.

seeks to divert attention by reciting figures of how many documents it has produced in this litigation. (*See* Dkt. No. 6270 at 26-29.) Because what has been produced tells nothing about what was destroyed, courts routinely reject this kind of irrelevant argument. *See, e.g., Washington Alder LLC v. Weyerhaeuser Co.*, No. CV 03-753-PA, 2004 WL 4076674, at *2 (D. Or. May 5, 2004) (“Defendant asserts that it has produced 400,000 pages of discovery in these actions. However, as good lawyers know, even large cases frequently turn on just a handful of documents. If those few critical documents are destroyed, that loss is not offset by producing 400,000 documents of lesser significance.”).

Similarly, instead of addressing the destruction of workpapers for important OIG reports, DOJ proclaims that OIG workpapers categorically are “wholly irrelevant.” (Dkt. No. 6270 at 13.) Of course, one cannot know that without knowing what was in the workpapers. Moreover, surviving OIG workpapers *do* contain important and relevant evidence; many have been marked as deposition exhibits. For example, some of these documents provide clear evidence that the Government had detailed knowledge of the “spreads”—including invoices—for the specific drugs at issue in these cases. (*See* Ex. P; Ex. Q).⁷ Other workpapers contain “survey” documents that record relevant, contemporaneous statements by Medicaid officials. (*See, e.g.,* Ex. R (Missouri response to OIG’s report on the “DOJ AWP”: “infusion providers were using spread to cover ancillary costs”).)

Finally, DOJ touts its retention of “the Official Rulemaking Record” for certain drug regulations, and incorrectly suggests that defense counsel have not looked at this information.

(Dkt. No. 6270 at 27.) Counsel for Dey, Roxane, and Abbott have coordinated their review of

⁷ DOJ claims that it produced certain electronic spreadsheets created during a 1994 AWP audit. (*See* Dkt. No. 6097 at 17-18; Dkt. No. 6270 at 34.) While Mr. Chesser clearly testified that he created spreadsheets that displayed the discount from AWP on an NDC basis (Dkt. No. 6097 at Ex. MMM at 603-04), the documents produced by the Government do not show that information. When Abbott followed up with DOJ, it was told “we sent you the electronic files that Mr. Chesser was able to find which appeared to comprise the material you were requesting - there was no material that was withheld.” (Ex. S.)

this information. DOJ merely placed these boxes in a room and allowed Defendants to review, without documenting precisely which documents were reviewed. Accordingly, DOJ cannot represent what defense counsel has reviewed. Indeed, if defense counsel had not reviewed this information, it is hard to explain how they could have marked documents from these files as deposition exhibits and included them in interrogatory responses. (*See, e.g.*, Ex. T (Abbott Ex. 299); Ex. U (Abbott Ex. 300); Ex. V (Abbott Ex. 1109); Ex. W (Abbott response to Ven-A-Care interrogatory on public disclosure).) In any event, these records were not near the volume or comprehensiveness as DOJ suggests, and the Government continues to withhold the most useful information from these files under claims of privilege.

C. Spoliation Of Claims And Other Payment-Related Data.

Finally, DOJ's response confirms that vital payment-related information is lost.

State Medicaid Data. DOJ's claim that it "has produced to defendants data regarding every NDC (National Drug Code) for every state for every time period for which damages are sought in these cases" (Dkt. No. 6270 at 29-30), is based exclusively on "aggregate data" that omits critical information, including whether claims were paid on the basis of a compendia price. To determine that, DOJ needs actual claims data from the states. There is no dispute that there are large gaps in this data.⁸ These motions concern the missing data, not what was produced.

Medicare Pricing Arrays. DOJ is well aware that even those contractors that produced arrays were not able to produce arrays for much of the relevant time period. These arrays are "missing." As to those contractors that did not produce any arrays, Defendants can only assume that DOJ would have attempted to obtain by now the information necessary to prove its case.

⁸ DOJ incorrectly argues that Abbott contends the Government produced claims data from only ten states. In fact, what Abbott said was that "Plaintiffs now wish to use a patchwork of claims data from *only ten states* to extrapolate Medicaid damages *nationwide*." (Dkt. No. 6097 at 14.) Abbott's motion *in limine* takes issue with the Government expert's selective use of the still-incomplete claims data he had. (*See* Dkt. No. 6177 at 14-18.)

State MACs. There can be no dispute that state MAC evidence is largely unavailable. Numerous states were unable to determine whether and, if so, how MACs were established for the products at issue. (*See* Dkt. No. 6097 at 19, Appx. C (testimony from Dubberly, Terrebonne, Kramer, Cheloha, Haase, Nesser, Anderson, Iverson, Hayashi, Hautea-Wimpee).)

In sum, DOJ cannot seriously dispute that spoliation of evidence occurred here. And again, it is likely that what is known to be lost is only the tip of the iceberg.

IV. THE GOVERNMENT’S POST-HOC “RELEVANCE” ARGUMENTS ARE INACCURATE AND HAVE ALREADY BEEN REJECTED BY THIS COURT.

Apparently realizing that its preservation efforts were woefully inadequate, DOJ spends over half its brief contesting the “legal relevancy of the material” that was spoliated. (Dkt. No. 6270 at 2.) Courts routinely reject such after-the-fact assertions of irrelevance to excuse the destruction of evidence. Relevance is a determination for a court to make; parties cannot short-circuit that decision by unilaterally deciding what can be destroyed as “irrelevant.” *See Leon*, 464 F.3d at 956-57 (noting district court found “Dr. Leon did not have the authority to make unilateral decisions about what evidence was relevant in this case,” and affirming district court’s spoliation sanctions); *Ogin v. Ahmed*, 563 F. Supp. 2d 539, 545 (M.D. Pa. 2008) (issuing sanctions for spoliation when defendants “unilaterally made the decision that the driver’s logs were irrelevant and destroyed the records”).

There can be no dispute that the evidence at issue here is discoverable; it goes to the heart of the matter.⁹ Indeed, this Court already ruled as much. DOJ’s contrary argument boils down to the absurd proposition that, except for data showing how Medicare and Medicaid paid for the

⁹ That is why, for example, DOJ undertook a “non-stop agenda of meetings and telephone conferences with numerous parties,” “witness interviews across the country,” and “many” meetings with state officials. DOJ is not the only party permitted to gain discovery of the contemporaneous facts. *See Gagne v. Reddy*, 104 F.R.D. 454, 456 (D. Mass. 1984) (“relevancy is broadly construed at the discovery stage of litigation and a request for discovery should be considered relevant if there is *any* possibility that the information sought may be relevant to the subject matter of the action”) (citation omitted).

drugs, *no* evidence from state and federal agencies is either discoverable or relevant. DOJ has put forward that argument from the very moment this case was unsealed. (*See* Dkt. No. 3108 at 7-10.) Over and over, DOJ has tried to keep discovery as a one-way street, thwarting discovery of “government knowledge,” raising the *exact same arguments* it advances here. The Court squarely rejected those arguments at the outset of the case. It rejected them throughout discovery. (*See, e.g.*, Dec. 4, 2008 Hrg. at 29-45) (overruling DOJ’s relevance objections and granting motion for CMS testimony on, among other things, CMS’s interpretation of AWP, CMS’s response to Ven-A-Care’s *qui tam*, why CMS continued to approve state plans with discount levels different than survey results, and cross-subsidization).) And it reaffirmed those rulings as recently as November 5, 2008, stating:

Although the government knowledge defense may not ultimately prevail, Abbott has the right during discovery to see documents reflecting the government’s knowledge of spreads in order to mount the defense.

(Dkt. No. 5665 at 15.) DOJ identifies no reason to revisit those rulings.

In fact, evidence of government policy, actions, and knowledge has proven not just discoverable, but admissible and even dispositive in AWP cases. In its summary judgment decision on the Massachusetts litigation, for example, this Court analyzed evidence regarding the Commonwealth’s understanding about the difference between WAC prices and market prices. The Court eventually concluded that, “[w]ith respect to the post-2002 period, a government knowledge defense is viable because the government decided to continue using WACs as a policy matter.” *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 152 (D. Mass. 2008). DOJ’s position on relevance would have blocked all this evidence from consideration. Likewise, in a recent hearing in the New York Counties litigation, the Court commented at length about the potential legal import of government knowledge evidence. (*See* July 8, 2009 Hrg. at 65-82.)

Similar issues exist in these cases. For example, Defendants have developed substantial

evidence that Medicaid and Medicare continued to use AWP prices throughout the relevant time period for policy reasons, including the expressed desire to cross-subsidize inadequate or non-existent dispensing or administration fees. (*See* Dkt. No. 6097 at 5 n.4 (Powerpoint presentation).) DOJ makes no effort to explain how such evidence could possibly be “irrelevant” to these cases. And just as the Court learned in the New York Counties case that CMS failed to adhere to its FUL regulations, evidence here suggests that CMS, despite inquiries from states and even Ven-A-Care, failed altogether to fulfill its responsibility to set FULs for injectable and infusion products. (*See* Ex. X at 243-48, 264-67 (CMS’s S. Gaston).)

DOJ’s response that its drug payment “policies are developed and implemented on the public record” is both a misleading oversimplification and a paltry excuse for destroying information. (Dkt. No. 6270 at 2.) That certain aspects of policymaking are subject to disclosure obligations does not justify destroying everything else. From recent proceedings in the New York Counties litigation, the Court knows that it cannot simply rely upon what the Federal Register says to determine what the Government actually did on matters pertinent to Medicare and Medicaid drug policy. (July 8, 2009 Hrg. at 28.) Nor can the Court simply accept the DOJ’s version of what, allegedly, the Government knew or did in this area. (*See id.* at 92-94.)

Indeed, when Tom Scully testified during his deposition that Congress exempted infusion drugs from the new ASP methodology in order to “freeze . . . some level of cross-subsidy,” he referred to it as “[a]nother piece of sausage” (Ex. Y at 366-67)—perhaps referring to Mark Twain’s famous quip that “those that respect the law and love sausage should watch neither being made.” Similarly, CMS’s Kathleen Buto testified that HCFA had a policy of cross-subsidization even though it was not reflected in the public record. When asked if HCFA’s 1991 regulation was meant to cross-subsidize practice costs, Ms. Buto admitted this was the case even

though HCFA's final rule did not explicitly state that. (Ex. Z at 308-09 ("It looks to me as if we dodged the question. . . . As a general matter, not related per se to this issue, the government doesn't like to pay for some things under one mechanism that was intended for one use and sort of overpay there in order to compensate for other costs. In reality it happens.").)

A CMS "decision memorandum" on its "Review of Medicaid Drug State Plan Amendments"—the final version of which DOJ withheld for more than a year under the deliberative process privilege until the Special Master ordered its production—provides another example. (Ex. AA (draft); Ex. BB (final).) This document reflects a clear understanding and acquiescence on the part of CMS to permit states to continue paying what it now calls "mega-spreads" for generic drugs. (*See* Dkt. No. 5173 at 2-6; Dkt. No. 5813 at 11-12.) Notably, this "decision memorandum" cannot be found anywhere in the public record.

This type of government-policy evidence has been a focus of every AWP case to proceed to trial to date. State trial courts have consistently rejected efforts to keep such evidence from the jury.¹⁰ This Court, too, has recognized the importance of evidence DOJ claims is irrelevant:

[I]t is unbelievably fact-intensive and difficult to go through what the Medicaid policies are. It is not just a question of law. It's who knew what, how did it happen, when did the policies change? It's hard, it's really hard, and we're working through that right now. So if there are other states that look like that, that's going to be—it's going to be state by state: What did they know, when did they know it, what was the statutory scheme?

(Nov. 13, 2008 Hrg. at 10.)

A fair resolution of these cases requires a complete factual record to explain why the

¹⁰ (*See, e.g.*, Ex. CC at ¶ 10) (denying Kentucky's motion to exclude "government knowledge evidence" and permitting defendants to introduce "evidence of cross-subsidization" and "evidence that pharmacy participation in the Medicaid program was a concern"); Ex. DD at 3 (Kentucky case: "The Defendants have framed the questions appropriately: 1. Was the Commonwealth deceived? and 2. Was reimbursement to Kentucky pharmacies inflated due to the Defendants' misconduct or based on well-informed policy choices?"); Ex. EE at 6 (Wisconsin case: "Plaintiff's argument that '[a]n untrue statement is untrue regardless of whether the listener knows it is untrue' . . . begs the question. How is a statement 'untrue' in the first place, if the speaker and listener are using terms they mutually understand because they have agreed on their meaning- that is, they have together developed the definitions, either expressly or tacitly, such that they have a common understanding?").)

programs paid what they did for drugs. *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d 164, 174-75 (D. Mass. 2007) (“accepting disputed factual propositions about a case ‘not tested in the crucible of trial is a sharp departure from standard practice’”). Tellingly, when it is not making excuses for spoliation, even DOJ claims the Court must have a “fully developed factual record” of government knowledge-related issues. The day after filing its response to Defendants’ spoliation motions, DOJ advised this Court that “[a]ny findings of fact regarding the government’s knowledge or considerations should be made in the context of a fully developed factual record.” (Ex. FF at 9.) The Court does not have a “fully developed factual record” in these cases because the Government destroyed the evidence necessary to compile that record.

V. THE REQUESTED SANCTIONS ARE REASONABLE AND APPROPRIATE.

The Court should find that spoliation has occurred and that sanctions are warranted. Even if the Court cannot resolve all of the spoliation-related issues—including many issues that may need to be resolved at trial—entering a finding of spoliation will streamline and simplify further proceedings. *See Miller*, 2007 WL 172327, at *6-7 (entering findings of spoliation).

Regardless of whether additional sanctions may be appropriate later, the destruction of claims data warrants an immediate sanction. Courts regularly impose sanctions for spoliation of damages evidence.¹¹ For example, in *United Medical Supply*, the United States spoliated information relevant to the plaintiff-contractor’s damage claims. As a spoliation sanction, the Court held that the United States was not permitted to either cross-examine the plaintiff’s expert *or introduce its own expert testimony* regarding certain “gaps” in evidence created by the Government’s spoliation of evidence. *See* 77 Fed. Cl. at 275. The same result is appropriate

¹¹ *See, e.g., Jones v. Hawley*, 255 F.R.D. 51, 54 (D.D.C. 2009) (imposing adverse inference where plaintiffs’ lost documents went “to the very heart of their claims for damages, and there [was] no substitute for them which the defendants could use or find”); *Ashford v. E. Coast Express Eviction*, Civ. A. No. 06-1561(RJL/JMF), 2008 WL 4517177, at *3 (D.D.C. Oct. 8, 2008).

here. As a spoliation sanction, DOJ should not be permitted, through expert testimony, to “fill the gaps” in evidentiary proofs that it has spoliated. *Id.*; *Jones*, 255 F.R.D. at 54.¹²

Likewise, Defendants should not bear the burden of the Government’s spoliation. The Court can and should now order that the burden of proof be shifted to Plaintiffs on all questions of government knowledge, policy, acquiescence, or approval.¹³ Because state and federal agencies continued using compendia prices for years, even decades, after evidence surfaced that they were not reliable proxies of acquisition cost (particularly for generic products), it is entirely reasonable to assign Plaintiffs the burden of proving that Medicare and Medicaid did not acquiesce in the payment of margins now sought from Defendants. In short, given extensive evidence that no one was “fooled” about AWP, Plaintiffs should have the burden of explaining why the continued reliance on compendia prices was not a deliberate policy decision—particularly since the Government spoliated evidence necessary to fairly adjudicate that issue.

Finally, DOJ cannot, and does not, deny that monetary sanctions should be imposed if there is a finding of spoliation. Such sanctions are “frequently invoked to reimburse an aggrieved party for the price of investigating and litigating document destruction.” *Capellupo v. FMC Corp.*, 126 F.R.D. 545, 552-53 (D. Minn. 1989) (imposing *twice* the total amount of attorneys’ fees and costs); *see also United Med. Supply Co.*, 77 Fed. Cl. at 275-76.

¹² None of the cases DOJ cites supports its contention that spoliation of damages evidence does not “properly implicate a spoliation sanction.” (Dkt. No. 6270 at 18, 29.) Two hold that sanctions are inappropriate where the same evidence that was destroyed is available in a different form, which is not the case here. *See Loveless v. John’s Ford, Inc.*, 232 F. App’x 229, 236 (4th Cir. 2007); *Lampi Corp. v. Am. Power Prods., Inc.*, No. 93 C 1225, 2004 WL 1656547, at *2 (N.D. Ill. July 22, 2004). And while the Government argues that *Beatrice Foods Co. v. New Eng. Printing & Lithographing Co.*, 899 F.2d 1171, 1175 (Fed Cir. 1990) shows that “the court ultimately looked to available evidence to estimate damages” (Dkt. No. 6270 at 18), that is exactly what Abbott seeks here—a determination of damages solely based on claims for which underlying claims data is available.

¹³ *See Nation-wide Check Corp. v. Forest Hills Distribs.*, 692 F.2d 214, 218 (1st Cir. 1982) (an adverse inference “plac[es] the risk of an erroneous judgment on the party that wrongfully created the risk”); *cf. Nat’l Ass’n of Radiation Survivors v. Turnage*, 115 F.R.D. 543, 557 (N.D. Cal. 1987) (“Where one party wrongfully denies another the evidence necessary to establish a fact in dispute, the court must draw the strongest allowable inferences in favor of the aggrieved party.”).

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CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 12th day of August, 2009.

/s/ David S. Torborg
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